

## REQUEST FOR RECALCULATION OF PATENT TERM ADJUSTMENT IN VIEW OF WYETH\*

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|--------------------------------------------------------------------------------------------------------------|-------------------------------------|
| Attorney Docket Number: <b>E-181-2002/0-US-03</b>                                                            | Patent Number: <b>7,606,623</b>     |
| Filing Date (or 371(b) or (f) Date): <b>January 4, 2006</b>                                                  | Issue Date: <b>October 20, 2009</b> |
| First Named Inventor: <b>Christy L. Ludlow</b>                                                               |                                     |
| Title: <b>Methods and devices for intramuscular stimulation of upper airway and swallowing muscle groups</b> |                                     |

PATENTEE HEREBY REQUESTS RECALCULATION OF THE PATENT TERM ADJUSTMENT (PTA) UNDER 35 USC 154(b) INDICATED ON THE ABOVE-IDENTIFIED PATENT. THE PATENTEE'S SOLE BASIS FOR REQUESTING THE RECALCULATION IS THE USPTO'S PRE-WYETH INTERPRETATION OF 35 U.S.C. 154(b)(2)(A).

Note: This form is only for requesting a recalculation of PTA for patents issued before March 2, 2010, if the sole basis for requesting the recalculation is the USPTO's pre-Wyeth interpretation of 35 U.S.C. 154(b)(2)(A). See Instruction Sheet on page 2 for more information.

Patentees are reminded that to preserve the right to review in the United States District Court for the District of Columbia of the USPTO's patent term adjustment determination, a patentee must ensure that he or she also takes the steps required under 35 U.S.C. 154(b)(3) and (b)(4) and 37 CFR 1.705 in a timely manner.

\**Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir., Jan. 7, 2010).

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|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------|
| Signature <b>/Susan S. Rucker/</b>                                                                                                                                                                                                                                                                                       | Date <b>February 2, 2010</b>      |
| Name (Print/Typed) <b>Susan S. Rucker</b>                                                                                                                                                                                                                                                                                | Registration Number <b>35,762</b> |
| <p><b>Note:</b> Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required in accordance with 37 CFR 1.33 and 11.18. Please see 37 CFR 1.4(d) for the form of the signature. If necessary, submit multiple forms for more than one signature, see below*.</p> |                                   |
| <input checked="" type="checkbox"/> *Total of <u>1</u> forms are submitted.                                                                                                                                                                                                                                              |                                   |

The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and 1.14. This collection is estimated to take 12 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

**Instruction Sheet for:  
REQUEST FOR RECALCULATION OF PATENT TERM ADJUSTMENT  
IN VIEW OF *WYETH*\***  
(Not to be Submitted to the USPTO)

**This form is only for requesting a recalculation of PTA for patents issued before March 2, 2010, if the sole basis for requesting the recalculation is the USPTO's pre-*Wyeth* interpretation of 35 U.S.C. 154(b)(2)(A).**

**This form must be filed within 180 days of the day the patent was granted, with the following exception:**

Patentees who received a decision from the USPTO under the USPTO's pre-*Wyeth* interpretation of 35 U.S.C. 154(b)(2)(A) may file a request for reconsideration of that decision if such a request for reconsideration is filed within **two months** of the date of the decision (37 CFR 1.181(f)). If the patentee's sole basis for requesting reconsideration of the decision is the USPTO's pre-*Wyeth* interpretation of 35 U.S.C. 154(b)(2)(A), the request for reconsideration need only state that reconsideration is being requested in view of *Wyeth* (this form may be used for this purpose if it is filed within **two months** of the date of the decision from the USPTO).

**Do not use this form if the application has been allowed, but not yet issued as a patent.**

- 1. For patents issued before March 2, 2010:** A request for reconsideration under 37 CFR 1.705(d) and the fee set forth in 37 CFR 1.18(e) are not required, provided that the patentee's sole basis for requesting recalculation of the PTA in the patent is the USPTO's pre-*Wyeth* interpretation of 35 U.S.C. 154(b)(2)(A) and this form is filed within 180 days of the day the patent was granted.
- 2. For patents issued on or after March 2, 2010 (do not use this form):** Patentees seeking a revised PTA in a patent issued on or after March 2, 2010, must file a request for reconsideration under 37 CFR 1.705(d) that complies with the requirements of 37 CFR 1.705(b)(1) and (b)(2) within two months of the day the patent issued.

For more information, see "Notice Concerning Calculation of the Patent Term Adjustment With Respect to the Overlapping Delay Provision of 35 U.S.C. 154(b)(2)(A)" available on the USPTO Web site at <http://www.uspto.gov/patents/law/notices/2010.jsp>.

\**Wyeth v. Kappos*, No. 2009-1120 (Fed. Cir., Jan. 7, 2010).

## Privacy Act Statement

The **Privacy Act of 1974 (P.L. 93-579)** requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (i.e., GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.